

Docket No. 7156/52427-AB/JPW/GJG/DNS

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant : Don Fishbein  
Serial No. : 10/799,197 Examiner: Amy A. Lewis  
Filed : March 12, 2004 Group: 1614  
For : USE OF OXANDROLONE IN THE TREATMENT OF BURNS  
AND OTHER WOUNDS

1185 Avenue of the Americas  
New York, New York 10036

Commissioner for Patents  
P.O. Box 1450  
Alexandria VA 22313-1450

Sir:

**TERMINAL DISCLAIMER**

Petitioner Savient Pharmaceuticals, Inc., having a place of business at One Tower Center Boulevard, 14<sup>th</sup> Floor, East Brunswick, NJ 08816, the sole assignee of record of the entire right, title, and interest in and to the above-identified application by virtue of an Assignment from Don Fishbein to Bio-Technology General Corp. recorded with the United States Patent and Trademark Office on June 19, 1998 at Reel 9271, Frames 0541-0543, a copy of which is attached hereto as **Exhibit 1**, and a change of name from Bio-Technology General Corp. to Savient Pharmaceuticals, Inc., recorded with the United States Patent and Trademark Office on January 16, 2004 at Reel 14871, Frames 0808-0813, a copy of which is attached hereto as **Exhibit 2**, both of which were filed in connection with parent U.S. Serial No. 08/985,734, filed December 5, 1997, now U.S. Patent 6,576,659, issued June 10, 2003, of which the subject application claims priority, hereby disclaims, except as provided below, the terminal portion of the statutory term of any patent granted on the subject application which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. §154 to §156

05/22/2006 AKELECH1 00000016 10799197

01 FC:1814

130.00 OP

**BEST AVAILABLE COPY**

Applicant: Don Fishbein  
Serial No.: 10/799,197  
Filed: March 12, 2004  
Page 2

and §173 of commonly assigned U.S. Patent Nos. 6,576,659 and 6,828,313 and of any patent issued from commonly assigned U.S. Serial No. 10/799,264.

Petitioner hereby agrees that any patent granted on the subject application shall be enforceable only for and during such period that U.S. Patent Nos. 6,576,659 and 6,828,313, and any patent issued on U.S. Serial No. 10/799,264, are commonly owned and that this agreement will run with any patent granted on the subject application and be binding upon the grantee, its successors and assigns.

In making the above disclaimer, Petitioner does not disclaim the terminal portion of any patent granted on the subject application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. §154 to §156 and §173 of U.S. Patent Nos. 6,576,659 and 6,828,313 and any patent issued from U.S. Serial No. 10/799,264, in the event that such patents later expire for failure to pay a maintenance fee, are held unenforceable, are found invalid by a court of competent jurisdiction, are statutorily disclaimed in whole or terminally disclaimed under 37 C.F.R. §1.321, have all claims canceled by a reexamination certificate, are reissued, or are in any manner terminated prior to the expiration of their full statutory term.

I certify that I have reviewed the attached Assignment and Change of Name document, and that, to the best of my knowledge and belief, Savient Pharmaceuticals, Inc. has the entire right, title and interest in and to the subject application. I further certify that I am authorized to sign this Terminal Disclaimer on behalf of Savient Pharmaceuticals, Inc. as indicated.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these

Applicant: Don Fishbein  
Serial No.: 10/799,197  
Filed: March 12, 2004  
Page 3

statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that any such willful false statement may jeopardize the validity of the application or any patent issued thereon.

SAVIENT PHARMACEUTICALS, INC.

Date: May 12, 2006

By: 

Printed Name: \_\_\_\_\_

**Philip K. Yachmetz**  
**Executive Vice President**  
**Chief Business Officer**

Title: \_\_\_\_\_

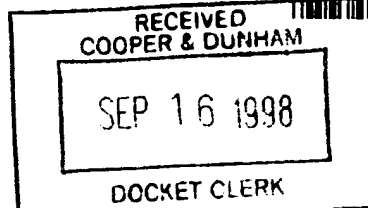


*JPW*  
**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**  
ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

SEPTEMBER 09, 1998

PTAS

COOPER & DUNHAM LLP  
JOHN P. WHITE  
1185 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036



\*100755217A\*

**UNITED STATES PATENT AND TRADEMARK OFFICE**  
**NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT**

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 06/19/1998

REEL/FRAME: 9271/0541  
NUMBER OF PAGES: 3

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:  
FISHBEIN, DON

DOC DATE: 06/17/1998

ASSIGNEE:  
BIO-TECHNOLOGY GENERAL CORP.  
70 WOOD AVENUE SOUTH  
METRO PARK FINANCIAL CENTER  
ISELIN, NEW JERSEY 08830

SERIAL NUMBER: 08985734  
PATENT NUMBER:

FILING DATE: 12/05/1997  
ISSUE DATE:

TONYA LEE, EXAMINER  
ASSIGNMENT DIVISION  
OFFICE OF PUBLIC RECORDS

07-01-1998

Docket No. 52427/JPW/SA

FORM PTO-1595 (Substitute)

(Rev. 8-96)

To the Honorable Commissioner of Patents

1. Name of conveying party(ies):

Don Fishbein

Additional name(s) of conveying party(ies) attached?

☐ Yes☒ No

MRD 6-22-98

3. Nature of Conveyance:

☒

Assignment

☐

Merger

☐

Security Agreement

☐

Change of Name

☐

Other

Execution Date(s):

4. Application number(s) or patent number(s): If this document is being filed together with a new application, the execution date(s) of the application is(are):

A. Patent Application No.(s) 08/985,734

B. Patent No.(s)

Additional numbers attached?

☐ Yes☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: John P. White

Internal Address: Cooper &amp; Dunham LLP

Street Address: 1185 Avenue of the Americas

City/State/Zip: New York, New York 10036

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR §3.41): \$ 40.00

☐

Enclosed

☒

Authorized to be charged to deposit account

8. Deposit account number:

03-3125

9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

John P. White

Name of Person Signing

Signature

June 19, 1998

Date

Total Number of pages including cover sheet, attachments and document: 3

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

John P. White

Reg. No. 28,678

Date

6/19/98

OMB No. 0651-0011 (exp. 4/94)

Mail documents to be recorded with required cover sheet information to:  
Commissioner of Patents and Trademarks  
Box Assignments

Washington, D.C. 20231

# Assignment

*In consideration of One Dollar (\$1.00). and other good and valuable considerations, the receipt of which is hereby acknowledged. I, the undersigned,*  
Don Fishbein, residing at 314 Scotch Plain, Westfield, New Jersey 07090

*Hereby sell, assign and transfer to* Bio-Technology General Corp.

*a corporation of the State of*

Delaware *having a place of business at* 70 Wood Avenue South, Metro Park  
Financial Center *in the County of* Middlesex *and State of* New Jersey 08830  
*its successors, assigns and legal representatives, the entire right, title and interest for all*  
*countries, in and to any and all inventions which are disclosed and claimed, and any and all*  
*inventions which are disclosed but not claimed, in the application for United States Patent,*  
*which has been executed by the undersigned on* June 17, 1998 *and is entitled*

THE USE OF OXANDROLONE IN THE TREATMENT OF BURNS AND OTHER WOUNDS  
(U.S. Serial No. 08/985,734, filed December 5, 1997, claiming priority  
of U.S. Provisional Application No. 60/032,414, filed December 5, 1996)

*and in and to said application and all divisional, continuing, substitute, renewal, reissue, and all*  
*other applications for U.S. Letters Patent or other related property rights in any and all*  
*foreign countries which have been or shall be filed on any of said inventions disclosed in said*  
*application; and in and to all original and reissued patents or related foreign documents which*  
*have been or shall be issued on said inventions;*

*Authorize and request the Commissioner of Patents of the United States to issue to said*  
*Assignee, the corporation above named, their successors, assigns and legal representatives, in*  
*accordance with this assignment, any and all United States Letters Patent on said inventions*  
*or any of them disclosed in said application;*

Agree that said Assignee may apply for and receive foreign Letters Patent or rights of any other kind for said inventions, or any of them; and may claim, in applications for said foreign Letters Patent or other rights, the priority of the aforesaid United States patent application under the provisions of the International Convention of 1883 and later modifications thereof, under the Patent Cooperation Treaty, under the European Patent Convention or under any other available international agreement; and that, when requested, without charge to, but at the expense of, said Assignee, its successors, assigns and legal representatives, to carry out in good faith the intent and purpose of this assignment, the undersigned or the undersigned's executors or administrators will, for the United States and all foreign countries, execute all divisional, continuing, substitute, renewal, reissue, and all other patent applications or other documents on any and all said inventions; execute all rightful oaths, assignments, powers of attorney and other papers; communicate to said Assignee, its successors, assigns and representatives, all facts known and documents available to the undersigned relating to said inventions and the history thereof; testify in all legal proceedings; and generally do everything possible which said Assignee, its successors, assigns or representatives shall consider desirable for aiding in securing, maintaining and enforcing proper patent protection for said inventions and for vesting title to said inventions and all applications for patents or related foreign rights and all patents on said inventions, in said Assignee, its successors, assigns and legal representatives; and

**Covenant** with said Assignee, its successors, assigns and legal representatives that no assignment, grant, mortgage, license or other agreement affecting the rights and property herein conveyed has been made to others by the undersigned, and that full right to convey the same as herein expressed is possessed by the undersigned.

Date: June 17, 1998 19

Witness: [Signature]

Julia McBrean

9 Iona Place

Aberdeen, NJ 07747

[Signature]

Don Fishbein

[L.S.]

PATENTS ONLY

Patent and Trademark Office

To the Honorable Commissioner of Patents and Trademarks: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):

Bio-Technology General Corp.

2. Name and address of receiving party(ies):

Name: Savient Pharmaceuticals, Inc.

Internal Address: 14th Floor

Street Address: One Tower Center Boulevard

City/State/Zip: East Brunswick, NJ 08816

Additional name(s) of conveying party(ies) attached?

☐ Yes ☒ No

3. Nature of Conveyance:

- ☐ Assignment ☐ Merger  
☐ Security Agreement ☒ Change of Name  
☐ Other

Execution Date(s): June 23, 2003

Additional name(s) & address(es) attached? ☐ Yes ☒ No

4. Application number(s) or patent number(s): If this document is being filed together with a new application, the execution date(s) of the application is(are):

A. Patent Application No.(s)  
SEE ATTACHMENT

B. Patent No.(s)  
SEE ATTACHMENT

Additional numbers attached? ☒ Yes ☐ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: John P. White

Internal Address: Cooper & Dunham LLP

Street Address: 1185 Avenue of the Americas

City/State/Zip: New York, New York 10036

6. Total number of applications and patents involved: 49

7. Total fee (37 CFR §3.41): ..... \$ 1,960.00

☐ Enclosed

☒ Authorized to be charged to deposit account

8. Deposit account number:

03-3125

DO NOT USE THIS SPACE

9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

John P. White

Name of Person Signing

Reg. No. 28,678

Signature

January 14, 2004

Date

Total Number of pages including cover sheet, attachments and document: 6

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

John P. White  
Reg. No. 28,678

1/14/04

Date



Page 1 of 3  
Continuation of Box 4 of Form PTO-1595 (Substitute)  
(recording name change from Bio-Technology General Corp.  
TO  
Savient Pharmaceuticals, Inc.)

Application No.	Application Date	Patent No.	Issue Date
06/752,441	July 3, 1985	4,831,120	May 16, 1989
07/320,320	March 7, 1989	4,997,916	March 5, 1991
07/539,367	June 15, 1990	5,112,744	May 12, 1992
07/692,630	April 29, 1991	5,116,616	May 26, 1992
07/317,434	March 1, 1989	5,126,252	June 30, 1992
07/194,424	May 13, 1988	5,143,836	September 1, 1992
07/780,353	October 22, 1991	5,147,789	September 15, 1992
07/822,054	January 14, 1992	5,151,364	September 29, 1992
07/449,125	December 8, 1989	5,162,217	November 10, 1992
07/635,413	January 3, 1991	5,198,361	March 30, 1993
07/790,485	November 12, 1991	5,242,812	September 7, 1993
07/842,740	February 27, 1992	5,246,847	September 21, 1993
07/840,578	February 24, 1992	5,256,546	October 26, 1993
07/526,397	May 21, 1990	5,270,030	December 14, 1993
07/912,213	July 10, 1992	5,270,195	December 14, 1993
08/029,030	March 10, 1993	5,360,729	November 14, 1994
08/058,241	May 4, 1993	5,455,158	October 3, 1995
08/370,461	January 9, 1995	5,540,911	July 30, 1996
08/261,750	June 17, 1994	5,593,860	January 14, 1997
08/340,045	November 14, 1994	5,637,495	June 10, 1997
08/459,356	July 2, 1995	5,670,371	September 23, 1997
08/259,569	June 14, 1994	5,679,320	October 21, 1997
08/450,014	May 25, 1995	5,759,816	June 2, 1998
08/400,544	March 8, 1995	5,763,215	June 9, 1998

Page 2 of 3  
Continuation of Box 4 of Form PTO-1595 (Substitute)  
(recording name change from Bio-Technology General Corp.  
TO  
Savient Pharmaceuticals, Inc.)

08/216,851	March 22, 1994	5,795,776	August 18, 1998
08/826,885	April 8, 1997	5,869,616	February 9, 1999
08/986,015	December 5, 1997	5,872,147	February 16, 1999
08/897,043	July 18, 1997	5,945,304	August 31, 1999
08/782,760	January 13, 1997	5,948,668	September 7, 1999
08/409,750	March 24, 1995	5,965,383	October 12, 1999
08/267,867	November 12, 1997	6,001,604	December 14, 1999
08/686,465	July 25, 1996	6,010,875	January 4, 2000
08/451,474	May 26, 1995	6,030,611	February 29, 2000
08/871,302	June 9, 1997	6,054,291	April 25, 2000
08/244,988	October 20, 1993	6,090,799	July 18, 2000
08/909,140	August 11, 1997	6,121,426	September 19, 2000
08/686,466	July 25, 1996	6,361,772	March 26, 2002
08/985,734	December 5, 1997	6,576,659	June 10, 2003
08/299,047	August 31, 1994	6,610,520	August 26, 2003
09/469,817	December 22, 1999	6,670,351	December 30, 2003
08/369,309	January 6, 1995	RE35724	February 3, 1998
29/040,830	June 28, 1995	Des. 403064	December 22, 1998

Page 3 of 3  
Continuation of Box 4 of Form PTO-1595 (Substitute)  
(recording name change from Bio-Technology General Corp.  
TO  
Savient Pharmaceuticals, Inc.)

Application No.	Application Date	Patent No.	Issued
08/023,248	February 13, 1998		
07/188,303	April 29, 1988		
09/492,971	January 27, 2000		
09/469,817	December 22, 1999		
10/052,961	January 16, 2002		
09/390,225	September 3, 1999		
10/011,377	October 22, 2001		

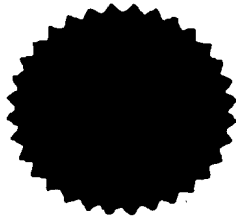
# Delaware

PAGE 1

*The First State*

I, HARRIET SMITH WINDSOR, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "BIO-TECHNOLOGY GENERAL CORP.", CHANGING ITS NAME FROM "BIO-TECHNOLOGY GENERAL CORP." TO "SAVIENT PHARMACEUTICALS, INC.", FILED IN THIS OFFICE ON THE TWENTY-FOURTH DAY OF JUNE, A.D. 2003, AT 9:30 O'CLOCK A.M.

A FILED COPY OF THIS CERTIFICATE HAS BEEN FORWARDED TO THE NEW CASTLE COUNTY RECORDER OF DEEDS.



*Harriet Smith Windsor*  
Harriet Smith Windsor, Secretary of State

0894913 8100

030416268

AUTHENTICATION: 2515430

DATE: 07-08-03



State of Delaware  
Secretary of State  
Division of Corporations  
Delivered 09:30 AM 06/24/2003  
FILED 09:30 AM 06/24/2003  
SRV 030416268 - 0894913 FILE

**CERTIFICATE OF AMENDMENT  
OF  
CERTIFICATE OF INCORPORATION  
OF  
BIO-TECHNOLOGY GENERAL CORP.**

\*\*\*\*\*

Bio-Technology General Corp., a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware, (the "Corporation"), DOES HEREBY CERTIFY:

FIRST: Articles FIRST and SECOND of the Certificate of Incorporation of the Corporation is hereby amended and replaced in its entirety with the following:

"FIRST: The name of the corporation is Savient Pharmaceuticals, Inc. (hereinafter referred to as the "Corporation").

SECOND: The address of the Corporation's registered office in Delaware is Corporation Trust Center, 1209 Orange Street, City of Wilmington, 19801, County of New Castle. The name of its registered agent at such address is The Corporation Trust Company."

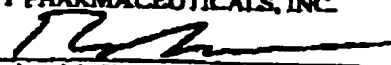
SECOND: The Certificate of Amendment of Certificate of Incorporation herein certified was duly adopted in accordance with the applicable provisions of Section 242 of the General Corporation Law of the State of Delaware.

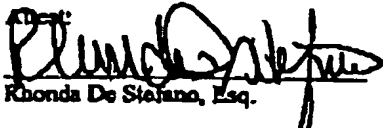
THIRD: The Certificate of Amendment herein certified was duly adopted at the annual meeting of the stockholders of the Corporation duly called and held, upon notice in accordance with Section 222 of the General Corporation Law of the State of Delaware, at which meeting the necessary number of shares as required by statute voted in favor of the amendment to the Corporation's Certificate of Incorporation.

IN WITNESS WHEREOF, the undersigned has caused this Certificate of Amendment of Certificate of Incorporation to be signed, under penalties of perjury, and the facts stated herein are true and correct.

Dated: June 23, 2003

SAVIENT PHARMACEUTICALS, INC.

By:   
Name: Robert M. Shaw  
Title: Executive Vice President and  
Chief Administrative Officer

  
Rhonda De Stefano, Esq.

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**